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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/599,687	09/08/2008	Yehuda Sharf	36806	2834

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EXAMINER

SZMAL, BRIAN SCOTT

ART UNIT	PAPER NUMBER
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3736

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/599,687	Applicant(s) SHARF, YEHUDA	
	Examiner Brian Szmaj	Art Unit 3736	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-56 is/are pending in the application.
 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-56 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 05 October 2006 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____. |
| 2) <input type="checkbox"/> Notice of Drafts, Person's Patent Drawing, Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>See Continuation Sheet</u> . | 6) <input type="checkbox"/> Other: ____. |

Continuation of Attachment(s) 3). Information Disclosure Statement(s) (PTO/SB/08), Paper No(s)/Mail Date :5/2/08; 9/16/09; 2/4/10; 5/24/10; 7/20/10; 9/16/10; 11/21/10.

Drawings

1. The drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims. Therefore, the state display including a presentation of states according to their relative context and including a history of states, as claimed in Claim 54, must be shown or the feature(s) canceled from the claim(s). No new matter should be entered.

Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as “amended.” If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either “Replacement Sheet” or “New Sheet” pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Claim Rejections - 35 USC § 101

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2. 35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 1-56 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter.

Based upon consideration of all of the relevant factors with respect to the claim as a whole, claim(s) 1, 40 and 56 are held to claim an abstract idea, and is/are therefore rejected as ineligible subject matter under 35 U.S.C. 101. The rationale for this finding is explained below: With respect to Claim 1, the only "machine" that is nominally recited are "positioning elements" that provide position signals. The method step of "determining the discrete state of labor" does not recite any use of a machine to perform the function. Therefore, the determining step can be adequately performed by a person, and therefore the claim is nonstatutory under 35 USC 101. Regarding Claims 40 and 56, there is no recitation of a machine or transformation, expressly or inherently, in either claim. With respect to Claim 56, the "positioning elements" can be reasonably interpreted as markers that are used to manually measure the distance therebetween during labor.

Claim Rejections - 35 USC § 112

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

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4. Claims 1-39 and 45 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The determining step in Claim 1 renders the claim indefinite. Based on the current claim language, it is unclear what is "responsive to said position signals", since the claim language can be reasonably interpreted as either the state of labor is responsive to the position signals, or the fetus inside the body is responsive to the position signals. Furthermore, it is unclear what has a "temporal resolution of better than 15 minutes". The current claim language can be reasonably interpreted as the position signals have a temporal resolution of better than 15 minutes, or the state of labor has a temporal resolution of better than 15 minutes.

Regarding Claim 33, the claim language states "wherein said position signals are acquired using a reference remote from said elements". It is unclear how a reference can be used to acquire position signals, since the reference does not provide any position signals with respect to the elements placed on the anatomical features. A reference merely provides a base signal that is used to provide a calibration signal to the system, and does not provide any positional information regarding the anatomical features being monitored.

Regarding Claims 43 and 44, both claims disclose "a norm", while independent Claim 40 has already disclosed "a norm". It is unclear if the "norm" in Claims 43 and 44 is different from the "norm" in Claim 40, or if it is the same "norm".

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Regarding Claim 45, it is unclear how the modifying a treatment step in Claim 40 can be further limited to “not modifying”, since it is unclear how the current claim language of Claim 40 would support “not modifying” since “not modifying” would require the identified relationship to be within the norm, but the current claim language of Claim 40 does not disclose such a limitation.

Claim Objections

5. Claim 40 is objected to because of the following informalities: “said parameter changing its relationship...the norm” should read as “a change in the relationship between the parameter and the norm” to be more concise. Appropriate correction is required.

Claim Rejections - 35 USC § 102

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

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7. Claims 40-48, 50 and 51 are rejected under 35 U.S.C. 102(b) as being anticipated by Garfield et al (2002/0193670 A1).

Garfield et al disclose a means for monitoring labor and further disclose collecting information about a labor process; generating a personalized progression representation based on the information; identifying a relationship between a parameter of the representation and a norm within 20 minutes of a change (the process is performed in real time); selectively modifying a treatment of the labor responsive to the identification; the identification comprises using computer circuitry; suggesting a modification using computer circuitry; identifying comprises identifying a parameter is outside the norm; identifying the parameter is inside the norm; selectively modifying comprises not modifying; generating the personalized progression comprises statistical analysis of the collected information; the statistical analysis comprises a long term analysis (over the entire time until birth); the statistical analysis comprises a short term analysis (measuring at that very moment); the personalized progression representation includes an expected rate of change; and the personalized progression representation includes an identification of at least three labor states. See Paragraphs 0078, 0080-0085, 0088-0093 and 0118.

8. Claim 56 is rejected under 35 U.S.C. 102(e) as being anticipated by Paltieli et al (2008/0167553 A1).

Paltieli et al disclose a means for monitoring a labor parameter and further disclose receiving, over time, a plurality of positional information from one or more positioning elements or tissue segments located at at least one of a cervix or a fetal

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head; determining at least one change in magnitude of positional information within a contraction; analyzing the at least one change; and determining a status of the labor based on the analysis. See whole document.

Claim Rejections - 35 USC § 103

9. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

10. Claims 49, 52, 53 and 55 are rejected under 35 U.S.C. 103(a) as being unpatentable over Garfield et al (2002/0193670 A1) as applied to claim 40 above, and further in view of Shine (6,440,089 B1).

Garfield et al, as discussed above, disclose a means of monitoring labor, but fail to disclose the generation of a histogram; the representation includes an indication that an individual maximum slope is about to be achieved; the indication comprises a display; and the indication comprises a display of the maximum slope.

Shine discloses a means of monitoring labor and further disclose the generation of a histogram; the representation includes an indication that an individual maximum slope is about to be achieved; the indication comprises a display; and the indication comprises a display of the maximum slope. See Figures 3 and 5.

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It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the means of Garfield et al to include the use of a histogram, and a display to display the maximum slope, and/or indicate the maximum slope is about to be achieved, as per the teachings of Shine, since it is well known in the art to use a display to convey information to a user, and the information can comprise graphs and histograms, as well as showing slopes of measured physiological parameters.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brian Szmaj whose telephone number is (571)272-4733. The examiner can normally be reached on Monday-Friday, with second Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Max Hindenburg can be reached on (571) 272-4726. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Brian Szmal/
Examiner, Art Unit 3736